



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,987	09/11/2000	John P. Vanden Heuvel	7024465PUR99	9345
7590	01/07/2004		EXAMINER	
Henry D Coleman COLEMAN SUDOL SAPONE P C 714 Colorado Avenue Bridgeport, CT 06605-1601			HUI, SAN MING R	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 01/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicant No.	Applicant(s)
	09/555,987	VANDEN HEUVEL ET AL.
	Examiner	Art Unit
	San-ming Hui	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 October 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-22 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 29, 2003 has been entered.

Claims 1-22 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boer et al. (US Patent 5,518,751) in view of Cook et al. (US Patent 5,554,646 from the IDS received September 6, 2000).

de Boer et al. teaches that unsaturated fatty acid, preferably CLA, in food compositions such as milk products are useful in treating disorders such as diabetes (See particularly col. 1, line 35 to 43).

de Boer et al. does not expressly teach particularly CLA is useful in a method of treating diabetes. de Boer et al. does not expressly teach that the conjugated linoleic acid is *trans,cis*-9,11-octadecainoic acid, *cis,cis*-9,11-octadecadienoic acid, or *trans,cis*-10,12-octadecadienoic acid can be incorporated into a composition such as a food composition. de Boer et al. does not expressly teach that the amount of the conjugated linoleic acid is about 1mg to about 10,000mg/kg of body weight in the invention.

Cook et al. teaches a method of adding conjugated linoleic acid (CLA) compounds into animal feed to reduce fat in the animal (see particularly claim 1). Cook et al. also teaches the conjugated linoleic acid compounds to be used may include *trans,cis*-9,11-octadecainoic acid or *cis,cis*-9,11-octadecadienoic acid or *trans,cis*-10,12-octadecadienoic acid (See particularly col. 4, line 48 to col.5 line 8). Cook et al. also teaches the amount of CLA be employed as 0.001g/kg to 1g/kg (See col. 5, line 9-13).

It would have been obvious to one skill in the art when the invention was made to employ CLA in a method of treating diabetes. It would have been obvious for one of

Art Unit: 1617

ordinary skill in the art at the time the invention was made to incorporate about 1mg to about 10,000mg/kg of body weight of the *trans*, *cis*-9,11-octadecenoic acid or *cis,cis*-9,11-octadecadienoic acid or *trans,cis*-10,12-octadecadienoic acid into a milk composition product useful in a method of treating diabetes.

One of ordinary skill in the art would have motivated to employ CLA in a method of treating diabetes because de Boer et al. clearly teaches unsaturated fatty acids preferably CLA are useful to treat disorders including diabetes (See particularly col. 1, line 35 to 43). Therefore, employing CLA would have been reasonably expected to be useful to treat diabetes.

One of ordinary skill in the art would have been motivated to incorporate the CLA compounds herein in the amounts herein into milk food composition products useful in a method of treating diabetes because CLAs, broadly, are known to be useful in a method and composition for treating diabetes. Therapeutic effects in the treatment of diabetes would have been reasonably expected when using any particular known CLA compounds including the compounds herein in a composition or method to treat diabetes.

Optimization of result effect parameters (e.g., amount and concentrations of composition ingredients to be employed) is obvious as being within the skill of the artisan, absent evidence to the contrary.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Semenkovich and Heinecke (Diabetes, 1997;46:327-334) in view of Steinhart (Journal of Chemical Education, 1996; 73(12):A302) and Cook et al.

Semenkovich and Heinecke teaches most diabetic patients die from macrovascular complications. Semenkovich and Heinecke also teaches that oxidative modification of lipoproteins in diabetic patients is enhanced; with this being one of the major risk of developing cardiovascular complications (macrovascular complication) in diabetic patients (See the abstract, also page 330, col. 1, second paragraph).

Semenkovich and Heinecke also teaches that antioxidants as potent inhibitors of lipoprotein lipid peroxidation and thereby reduce the lipoprotein oxidation products and cytotoxicity caused by those products (See particularly page 330, col. 1, second paragraph).

Semenkovich and Heinecke does not expressly teach the employment of CLA in a method to treat diabetes, or the symptoms of diabetes. Semenkovich and Heinecke does not expressly teach that the conjugated linoleic acid is *trans,cis*-9,11-octadecadienoic acid, *cis,cis*-9,11-octadecadienoic acid, or *trans,cis*-10,12-octadecadienoic acid can be incorporated into a composition such as food composition. Semenkovich and Heinecke does not expressly teach the amount of the conjugated linoleic acid as about 1mg to about 10,000mg/kg of body weight in the invention.

Steinhart teaches that CLA is a natural antioxidant (See page 3, last paragraph; also page 5, last paragraph).

Cook et al. teaches a method of adding conjugated linoleic acid (CLA) compounds into animal feed to reduce fat in the animal (see particularly claim 1). Cook et al. also teaches the conjugated linoleic acid compounds to be used may include *trans,cis*-9,11-octadecainoic acid or *cis,cis*-9,11-octadecadienoic acid or *trans,cis*-10,12-octadecadienoic acid (See particularly col. 4, line 48 to col.5 line 8). Cook et al. also teaches the amount of CLA be employed as 0.001g/kg to 1g/kg (See col. 5, line 9-13).

It would have been obvious to one skill in the art when the invention was made to employ CLA in a method of treating diabetes. It would have been obvious for one of ordinary skill in the art at the time the invention was made to incorporate about 1mg to about 10,000mg/kg of body weight of the *trans, cis*-9,11-octadecainoic acid or *cis,cis*-9,11-octadecadienoic acid or *trans,cis*-10,12-octadecadienoic acid into a food composition product useful in a method of treating diabetes.

One of ordinary skill in the art would have motivated to employ CLA in a method of treating diabetes because administering CLA to diabetic patients would have been reasonably expected to be useful in reducing the macrovascular complications in such patients due to CLA's known antioxidant effect. Reducing complications of the disease would be reasonably expected to be useful as an adjunctive treatment modality.

One of ordinary skill in the art would have been motivated to incorporate the specific CLA compounds herein, in the amounts herein recited, into milk food composition products useful in a method of treating diabetes because CLAs, broadly, are reasonably expected to be useful in a method and composition for treating diabetes

as discussed above. Therapeutic effects in the treatment of diabetes would have been reasonably expected when using any particular known CLA compounds, including those specific CLA compounds herein, in a composition or method to treat diabetes.

Optimization of result effect parameters (e.g., amount and concentrations of composition ingredients to be employed) is obvious as being within the skill of the artisan, absent evidence to the contrary.

Response to Remarks

Applicant's arguments filed October 29, 2003 averring the teaching of de Boer et al. being ambiguous and therefore not suggesting linoleic acid being useful in treating diabetes has been considered but not found persuasive because de Boer et al. teaches that unsaturated fatty acid, especially linoleic acid, whether it is conjugated or not, is useful in the treatment of diabetes (See col. 1, lines 35-42; particularly line 39 and 40). In this passage, de Boer et al clearly teaches that both conjugated or unconjugated linoleic acid is useful in treating diabetes.

Applicant's arguments filed October 29, 2003 averring hindsight arguments have been considered, but are not found persuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d

1392, 170 USPQ 209 (CCPA 1971). In the instant case, de Boer et al. clearly teaches CLA is one of the preferred fatty acid for treating disorders such as diabetes.

Applicant's remarks filed October 29, 2003 with regarding to whether any additional references cited in support of the examiner's position have been considered, but are not found persuasive because whether any additional references cited or the number of references cited in support of examiner's position is seen to be i) irrelevant to the patentability of the instant claims and ii) not the legal standard for rejection under 35 USC 103, i.e., the examiner is not required [emphasis added] to cite more than one reference in constructing the rejection under 35 USC 103.

Applicant's remarks filed October 29, 2003 with regarding to de Boer et al.'s failure to teach the capability of CLA in lowering glucose have been considered, but are not found persuasive. Any arguments drawn to unclaimed limitation is considered moot.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning when combining the teachings of de Boer and Cook, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, Cook teaches the herein claimed CLA is useful in reducing body fat and can be incorporated in food. Taken Cook and de Boer together, one of ordinary skill in the art would have been incorporated the

herein claimed CLA in food to treat obesity, which is associated with diabetes, and diabetes itself (from the teaching of de Boer), absent evidence to the contrary.

Applicant's arguments filed October 29, 2003 with regard to atherosclerosis and diabetes have been considered, but are not found persuasive. Applicant argues that i) only limited number of diabetic patients develop artherosclerosis and ii) CLA is not taught as effective in treating artherosclerosis and conclude that therefore, the combination of the cited prior art, i.e., Semenkovich, Steinhart, and Cook, would not render the instant claims obvious. As discussed in the action, Steinhart teaches CLA is a known antioxidant and is useful in inhibiting artherosclerotic process. Such teachings are seen to be consistent with that of Semenkovich and Cook. All three references, when taken together, would motivate one of ordinary skill in the art to employ CLA in treating the well-known complications of diabetes, such as artherosclerosis and obesity, in diabetic patients. Inhibiting the process of developing complications of diabetes is considered as one of the treatments for diabetes.

Applicant's remarks with regard to Khosla and Fungwe have been considered, but are not found persuasive. Khosla and Fungwe is published after the filing date of the instant application and therefore, is not a probative evidence for demonstrate non-obviousness.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



San-ming Hui
Patent Examiner
Art Unit 1617